

REMARKS

The amendment to claim 11 does not add new matter. The amendment finds support throughout the specification. For example, page 3, line 44 – page 4, line 2, states, “The process can be carried out in such a manner that in each case only filtration or stabilization of the aqueous medium takes place, or, in addition to the filtration, simultaneous stabilization takes place. Preferably, in addition to the filtration, stabilization also takes place.” The amendments to claims 18 – 22 do not add new matter; the claims have been amended to depend from claim 11. The cancelation of claims 12, 16, 17, 23, 24, 25, 26, and 27 does not affect the scope of any pending claim, and, therefore, does not add new matter. The cancelation is made without prejudice and without disclaimer of the canceled subject matter. The amendments to claims 14 and 15 merely clarify confusion caused by a typographical error. New claim 28 does not add new matter; the claim finds support throughout the specification, for example, on page 3, lines 15 – 42.

The amendments to the specification merely clarify confusion caused by typographical errors and do not add new matter.

The Office action rejects claims 11 – 27, citing 35 U.S.C §103(a); US 3,958,023 to Butterworth (hereinafter, “Butterworth”); US 6,117,459 to Van Den Eynde (hereinafter, “Van Den Eynde”), and BASF’s 60th Anniversary of Povidone (hereinafter, “Anniversary”).

The cited references do not provide any reason to arrive at a process involving passing a suspension consisting of a discontinuous phase and a continuous phase through a porous filter medium at a constant flow rate. The Office action misconstrues applicants Remarks of September 18, 2006. Applicants remarks were made in response to the Examiner’s assertion that claim 11 seemed to violate the laws of thermodynamics by reciting “at a constant flow rate.” Applicants explained that a person having ordinary skill in the art knows how to adjust the pressure to keep the flow rate constant. An invention is not obviated, however, because those skilled in the art would have the ability to make and use the invention in view of the inventors’ disclosure.

The Office action errs by not recognizing the distinction between mixing and compounding. It seems ample evidence has been presented and discussed in previous

responses to demonstrate the distinction. The Office action does not provide any evidence to the contrary. Instead, the Office action maintains the rejection based on the assertion that if Applicants intended something more to be read into the term “compounding,” the specification should have made that clear. Applicants respectfully direct the Examiner to MPEP §2111.01, which explains, “[i]n the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art.” *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003). Applicants respectfully submit the specification does not include an express intent to impart a novel meaning to the terms “compound,” “compounded,” and/or “compounding.” The terms are used in accordance with their ordinary and customary meanings attributed to them by those of ordinary skill in the art.

Butterworth teaches away from compounding. Butterworth explains, chill haze agents adsorb or coagulate and precipitate undesirable compounds. Either mechanism requires direct contact between the chill haze agent and the undesirable compound. A skilled artisan had no reason to assume sufficient direct contact between a chill haze agent and undesirable compounds would occur to facilitate adsorption or coagulation and precipitation of the undesirable compounds if the chill haze agent was compounded with a filter aid.

Anniversary provides no reason to abandon Butterworth’s teachings and to melt extrude cross-linked PVP or PVPP. On page 4, Anniversary mentions a technique, which seems to have been used to improve delivery of certain drugs. Anniversary mentions, “Kollidon grades have been found to provide a comprehensive and universal base for various types of drugs.” These Kollidon grades are not crosslinked grades. The Kollidon grades that are melt extruded are selected due to their thermoplasticity and balanced aqueous solubility properties. At column 1 of page 4, Anniversary states, “[b]ecause of the combination of high water uptake and insolubility, swelling is observed with crosslinked PVP when exposed to water while soluble PVP simply dissolves.”

From the enclosed text book, Bühler, Volker, Kollidon® Polyvinylpyrrolidone for the pharmaceutical industry, BASF, Ludwigshafen, February 1999 (4th edition), a person having ordinary skill in the art would understand there are two basic grades of PVP. The

Office action confuses the two grades in discussing Anniversary. First, there is the soluble Kollidon® grades called povidone or just PVP (see chapter 2, page 15ff), which can be used for solid solutions, such as melt extrusion (see page 89/90) and to which the paragraph “Drug melt extrusion” in Anniversary refers. Second, there is the insoluble Kollidon® grade called Crospovidone or crosslinked PVP or PVPP (see chapter 3, page 129ff), which is referred to in Anniversary as crosslinked PVP on top of page 4, left column, and mentioned for beverage filtration. For filtration of beer no water-soluble PVP grade can be used as this would be dissolved in the beer. Insoluble crosslinked PVP, which is not thermoplastic and not meltable in contrast to soluble PVP, is compounded with the thermoplastic polymer, polystyrene, in the present application.

Van Den Eynde does not compensate for the above-mentioned shortcomings. Therefore, the rejection fails to establish even a *prima facie* case of obviousness and should be withdrawn.

The Office action rejects claims 11, 13 – 16, and 18 – 27, citing 35 U.S.C. §112, first paragraph. The rejection is moot in view of the amendments. At page 1, lines 30 – 32, the specification explains filter aids should, during filtration, form a porous environment, which takes up the impurities to be eliminated and facilitates the outflow of the liquid phase. At page 2, lines 21 – 25, the specification explains certain beverages can be stabilized by adding substances, which bind, precipitate, or in other ways remove the materials causing the haze from the medium. The “or” regarding stabilization and/or filtering refers to a beverage, which might only need one step, because there is nothing to stabilize or nothing to filter. Generally, both functions are always present. However, a person of ordinary skill in the art would be able to do just one.

The Office action rejects claims 11 – 27, citing 35 U.S.C. §112, second paragraph. First, the Office action asserts it is “unclear what specific manipulative steps Applicants regard as their invention.” Claim 11 recites, “A method … comprising the step of passing a suspension … through a porous filter medium at a constant flow rate” Second, the Office action asserts it is unclear how dependent claims 12 and 17 further limit the claims from which they depend. Claim 12 and 17 are canceled. Third, the Office action asserts in claims 14 and 25 it is unclear what applicants intend by the recitations “polyvinylpolypyrrolidone” and “PVPP.” The amendment to claim 14 should

clarify this issue. Claim 25 is canceled.

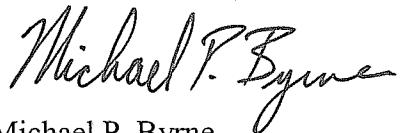
The Director is hereby authorized to charge any deficiency in fees filed, asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account 14-1437. Please credit any excess fees to such account.

The present application is in condition for allowance, and applicants respectfully request favorable action. In order to facilitate the resolution of any questions, the Examiner is welcome to contact the undersigned by phone.

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Enclosure: Bühler, Volker, Kollidon® Polyvinylpyrrolidone for the pharmaceutical industry, BASF, Ludwigshafen, February 1999 (4th edition).